



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2011-0941; FRL-9398-7]**

**RIN 2070-AB27**

### **Significant New Use Rule on Certain Chemical Substances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is finalizing the significant new use rule (SNUR) for three chemical substances which were the subject of premanufacture notices (PMNs) and subject to a TSCA section 5(e) consent order issued by EPA. This action requires persons who intend to manufacture (including import) or process any of these three chemical substances for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This final rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0941, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone

number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: [moss.kenneth@epa.gov](mailto:moss.kenneth@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Does this Action Apply to Me?**

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this final rule. Potentially affected entities may include, but are not limited to:

- Manufacturers or processors of the subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your

business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is finalizing a SNUR under TSCA section 5(a)(2) for three chemical substances that were the subject of PMNs and subject to a TSCA section 5(e) consent order issued by EPA. The SNUR is codified at 40 CFR 721.10515. The final SNUR designates as a significant new use manufacture (including import) or processing in the presence of the restrictions required in the consent order. The final SNUR for these

substances is based on and consistent with the provisions in the underlying consent order. This final action requires persons who intend to manufacture or process the chemical substances for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity

This rule was proposed in the **Federal Register** issue of January 23, 2013 (78 FR 4806) (FRL-6369-9). EPA received no public comments in response to the proposal for PMNs P-10-58, P-10-59, and P-10-60. Therefore, the Agency is issuing a final SNUR, as proposed that:

1. Revises significant new use requirements for specific uses identified in the consent order.

EPA did receive and comments on the remaining chemical substance in the proposed rule, PMN P-07-0204 (§ 721.10509), and will address that in a future, separate action.

*B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the final rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

## **III. Rationale and Objectives of the Final Rule**

### *A. Rationale*

During review of the PMNs submitted for the three chemical substances, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on these findings, a TSCA section 5(e) consent order requiring the use of appropriate exposure controls were negotiated with the PMN submitter. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent order. This SNUR is

promulgated pursuant to § 721.160. See the docket under docket ID number EPA-HQ-OPPT-2011-0941 for the corresponding consent orders.

*B. Objectives*

EPA is issuing this final SNUR for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this final rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA section 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

*<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.*

#### **IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors. To determine what would constitute a significant new use for the three chemical substances that are the subject of this SNUR, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

#### **V. Applicability of the Significant New Use Designation**

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore, EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing.

Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) (FRL-3658-5) for a more detailed discussion of the cutoff date for ongoing uses.

Any person, who began commercial manufacture or processing of the chemical substances for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR, must stop that activity before the effective date of the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

## **VI. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.



In the TSCA section 5(e) consent orders for the chemical substances regulated under this final rule, EPA has established restrictions in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These restrictions will not be removed until EPA determines that the unrestricted use will not present an unreasonable risk of injury or result in significant or substantial exposure or environmental release. This determination is usually made based on the results of the required or recommended toxicity tests. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. of the proposed rule lists tests required or recommended in each of the section 5(e) consent orders underlying the proposed section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VII. SNUN Submissions**

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN,

including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## **VIII. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances during the development of the direct final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2011-0941.

## **IX. Statutory and Executive Order Reviews**

### *A. Executive Order 12866*

This final rule establishes a SNUR for three new chemical substances that were the subject of PMNs and a TSCA section 5(e) consent order. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "*Regulatory Planning and Review*" (58 FR 51735, October 4, 1993).

### *B. Paperwork Reduction Act (PRA)*

According to PRA (44 U.S.C. 3501 *et seq.*), an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part

9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the

OMB control number in any correspondence, but do not submit any completed forms to this address.

*C. Regulatory Flexibility Act (RFA)*

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this final rule.

This final rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VIII. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

*D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted

by this final rule. As such, EPA has determined that this final rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132*

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

*F. Executive Order 13175*

This final rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this final rule.

*G. Executive Order 13045*

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

#### *H. Executive Order 13211*

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act (NTTAA)*

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

#### *J. Executive Order 12898*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

### **X. Congressional Review Act (CRA)**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 3, 2013.

Maria J. Doa,

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR parts 9 and 721 are amended as follows:

**PART 9--[AMENDED]**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following section in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation	OMB control No.
* * *	* *
<b>Significant New Uses of Chemical Substances</b>	
* * *	* *
721.10515	2070-0012
* * *	* *

\* \* \* \* \*

**PART 721--[AMENDED]**

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).



4. Add § 721.10515 to subpart E to read as follows:

**§ 721.10515 Partially fluorinated alcohol substituted glycols (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as partially fluorinated alcohol substituted glycols (PMN P-10-58, P-10-59, and P-10-60) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (manufacture and import of the PMN substances according to the chemical synthesis and composition section of the TSCA section 5(e) consent order, including analysis, reporting, and limitations of maximum impurity levels of certain fluorinated impurities; manufacture and import of P-10-58 and P-10-59 only as intermediates for the manufacture of P-10-60), and (q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of these substances, except the recordkeeping requirements for § 721.125 (b) and (c) do not apply to importers or processors when any one of the substances are contained in a formulation at less than 3 weight percent.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

[FR Doc. 2013-22112 Filed 09/10/2013 at 8:45 am; Publication Date: 09/11/2013]